K111686

AUG - 1 2011

Attachment (D) 510(k) Summary

This summary of 510(k) safety and effective information is being submitted in accordance with the requirement of SMDA and 21 CFR 807.92.

1. **Date Prepared**
   June 13, 2011

2. **Submitter's Information**
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3. **Device Information**

Proprietary Name:	A&D Medical UA-1000 Family Digital Blood Pressure Monitors
Common/Usual Name:	Blood Pressure Monitor
Classification name:	Non-invasive blood pressure measurement System 21 CFR 870-1130, Class II, 74DXN.

4. **Predicate Devices**
   A&D Model UA-787 Digital Blood Pressure Monitor with 510(k) number K012472
   A&D Model UA-851THW Digital Blood Pressure Monitor with 510(k) number K082734
   Predicate devices are designed and manufactured by the same company and facilities as the modified devices UA-1000 family.

5. **Device Description – Technological and Operaional Characteristics**
   UA-1000 family uses an inflatable cuff which is wrapped around the patient's upper arm. The cuff is inflated automatically by an internal pump in the device. The systolic and diastolic blood pressures are determined by oscillometric method. The deflation rate is controlled by the internal electronic-controlled exhaust valve. There is a quick exhaust mechanism so that the pressure of the cuff can be completely released. There is a maximum pressure safety setting at 300mmHg. The device will not inflate the cuff higher than 300mmHg. The UA-1000 family will turn on an irregular heartbeat indicator if an irregular heartbeat was detected during the measurement process. At the end of the measurement, the systolic and diastolic pressures with pulse rate are shown on the LCD and stored in the device memory. For UA-1030T, the results is also annoucment in voice. The cuff is also deflated automatically at the same time. There are two memory banks to separate the measurements in the morning time and in the evening time. UA-1020 and UA-1030T can conduct average function for 3 consecutive measurmenets automatically. The detail comparison among devices are listed below.

Features	UA-1010	UA-1020	UA-1030T
Powered by 4 AA size batteries and AC adaptor plug	Yes	Yes	Yes
Memory Size (90 measurements)	Yes	Yes	Yes
Time & Date	Yes	Yes	Yes
AM / PM Memory Banks	Yes	Yes	Yes
Pressure Indicator	Yes	Yes	Yes
Average of Measurements in Memory	Yes	Yes	Yes
IHB (Irrgular Heartbeat Detection)	Yes	Yes	Yes
Outside Demission (140 w x 60 h x 105 d in mm)	The same	The same	The same
Talking (Voice Announcement of Measurement Result)	No	No	Yes
Cuff Style	Opti	Opti	Easy Fit
LCD size (Viewing Area in mm)	43 × 48.5	62.5 ×7 2	62.5 × 72
Tricheck (Average of 3 consecutive measurements)	No	Yes	Yes

6. **Intended Use**

The A&D Medical UA-1000 family digital blood pressure monitors are intended for used by adults with 12 years older to measure the systolic and diastolic blood pressure and pulse rate.

The intended user and the indication for use of A&D Medial UA-1000 family as described in the labeling are the same as their predicated devices, UA-787 and UA-851THW.

7. **Summary of Substantial Equivalence**

Modifications from the predicate devices:

- Change the plastic molds so UA-1000 family has a different appearance
- Separate the memeory into two banks so it can calculate the measurements in the morning and in the evening separately.
- UA-1020 and UA-1030T have a tricheck capability so it can average 3 consecutive measurement results.
- UA-1030T adds a voice anuouncemnt capability at the end of the measurement.

Product Specification Comparison

Parameter	Predicate Devices (UA-787 & UA-851THW)	Modified Devices (UA-1000 Family)
Measurement Method	Oscillometric Method	No change – the same
Measurement Range	BP : 20 to 280 mmHg Pulse : 30 to 200 pulse/min	No change – the same
Accuracy	BP : +/- 3mmHg or +/- 2% of measured value, whichever is greater Pulse : +/- 5 % (pulse)	No change – the same

Pressurization Source	Automatic internal pump	No change – the same
Cuff Deflation Method	Constant speed electrical controlled exhaust valve (ECEV method)	No change – the same
Display Type	Liquid crystal display	No change – the same
Cuff Attachment Method	By plastic hose connected to monitor	No change – the same
IHB (Irregular Heartbeats Detection)	More than +/-25% to the mean interval of all pulse intervals	No change – the same
Power Source	6V DC, 4x1.5V AA batteries or AC adapter as an option	No change – the same
Battery Life	4 months with daily measurement	No change – the same
Operating Environment	50°F (10°C) to 104°F (40°C) 30 %RH to 85% RH	No change – the same
Storage Environment	14°F (-20°C) to 140°F (60°C) 10 %RH to 95% RH	No change – the same
Data Memory Size with Time & Date	30, 60 or 280 rmemories for UA-787 51 memories for UA-851THW	90 memories for all three models of UA-1000 family
Dimensions	UA-787 –163(W)×62(H)×112(D) UA-851THW – 150(W)×156(H)×120(D)	140(W)×60(H)×105(D) for all three models of UA-1000 family
Weight	UA-787 - 920 g (2.03 lb) without batteries UA-851THW - 940 g (2.07 lb) without batteries	UA-1010–265g UA-1020–285g UA-1030T–300g without batteries
Cuff Design	UA-851THW – D-ring cuffs UA-787 – U-shape cuffs	UA-1010 & UA-1020 – the same as UA-851THE UA-1030T -- the same as UA-787
Arm Size	UA-787 – 19 to 36 cm UA-851THW – 24 to 45 cm	UA-1030T – 23 to 37 cm UA-1010 & UA-1020 – 16 to 45 cm
Clock (Time/Date)	No	UA-1000 Family –Yes
Talking	No	No : UA-1010 & UA-1020 Yes : UA-1030T (3 languages – English, French, & Spanish)
AM/PM	No	UA-1000 Family –Yes
Pressure Indicator	UA-787 (No), UA-851THW (Yes)	UA-1000 Family –Yes
Wireless Radio Connectivity	UA-787 (No), UA-851THW (Yes)	No
Personal PC Analysis Software	UA-787 (No), UA-851THW (Yes)	No

Key Features Comparison

Parameter	**Predicate Devices (UA-787 & UA-851THW)**	**Modified Devices (UA-1000 Family)**
Field service	Not allowed	No Change – the same
Automatic zero at "START"	Yes	No Change – the same
Manual zero adjustment	Not allowed	No Change – the same

Calibration	Not allowed in the field	No Change – the same
Sterilization	Not needed	No Change – the same
Blood Pressure Reading Classfication Criteria	USA JNC VII	No change – the same

Substantial Equivalence Conclustion:
UA-1000 family digital blood pressure monitors have the following similarities to the predicate devices, UA-851THW and UA-787 digital blood pressure monitors, which previously received the 510(k) clearance.

- Same intended use.
- Same oscillometric method to determine the blood pressure & pulse rate
- Same inflation method – automatic internal pump
- Same deflation method – automatic electrical controlled exhaust valve
- Same materials, no new materials used
- Same manufacturing processes at the same facility

As a conclusion, the intended use of the modified device, UA-1000 family as described in its labeling, has not changed as a result of the modifications. The fundamental scientific technology of the modified device, UA-1000 family, has not changed, either. There is no significant difference that affects the safety or effectiveness of the modified device as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

A&D Engineering, Inc.
c/o Mr. Jerry Wang
Director of Engineering and Quality Affairs
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San Jose, CA 95131

AUG - 1 2011

Re: K111686
Trade/Device Name: UA-1000 Family Digital Blood Pressure Monitors
Regulatory Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: July 14, 2011
Received: July 19, 2011

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment B

Indications for Use

510(k) Number (if known):_____

Device Name: A&D Medical UA-1000 Family Digital Blood Pressure Monitors

Indications For Use:

Measure blood pressure (systolic and diastolic) and pulse rate.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111686